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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/03736	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL03/00774	International filing date (day/month/year) 25 September 2003 (25.09.2003)	Priority date (day/month/year) 25 September 2002 (25.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/10 and US Cl.: 606/143		
Applicant BY-PASS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

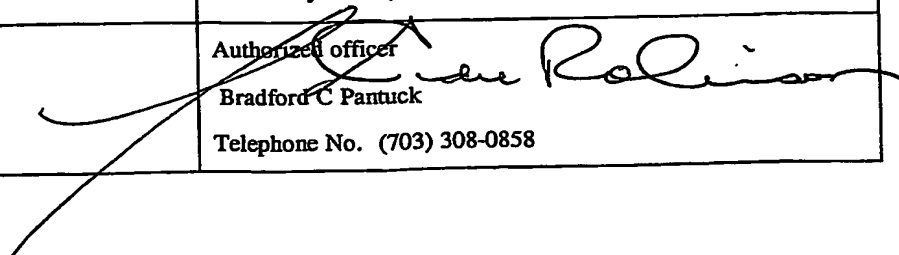
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21 April 2004 (21.04.2004)	Date of completion of this report 04 January 2005 (04.01.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Bradford C Pantuck Telephone No. (703) 308-0858

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description:
 pages 1-24 as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the claims:
 pages NONE, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages 25-31, filed with the demand
 pages NONE, filed with the letter of _____.
- ☒ the drawings:
 pages 1-19, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☒ complied with.
- ☒ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Inventive Step (IS)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Industrial Applicability (IA)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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Supplemental Box

To be used when the space in any of the preceding boxes is not sufficient)

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 6, 7, 13, 14, 20-23, 29, 31-33, 35, 40, and 41
The opinion as to Novelty was negative (No) with respect to claims 1-5, 8-12, 15-19, 24-28, 30, 34, and 36-39
The opinion as to Inventive Step was positive (Yes) with respect to claims 6, 7, 13, 14, 20-23, 29, 31-33, 35, 40, and 41
The opinion as to Inventive Step was negative (NO) with respect to claims 1-5, 8-12, 15-19, 24-28, 30, 34, and 36-39
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-41
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

1. Claims 1-5, 8-12, 15-19, 24-28, and 30 lack novelty under PCT Article 33(2) as being anticipated by NELSON et al. Regarding Claims 1, 16, 17, and 20, 25, and 26, Nelson's self-locking clip has a sharp extension at the bottom end of Fig. 2, which is capable of piercing body tissue. Base 16 interlocks with the sharp tip, as shown in Figure 5. The base 16 has an aperture, which accepts the sharp tip and guides it therethrough. There are multiple locking positions because of the teeth (widened parts) (18) [Fig. 5].

2. Regarding Claims 8, 9, 12, 15, 18, and 23, Nelson's connector clip has a tear location shown in Figure 17. The tear location is shown as a notched portion, which is thinner than the rest of the clip. The clip will tear at such a thinned portion before it tears anywhere else. The hooked section (118a), as shown in Figure 9 may or may not tear tissue. It is certainly capable of not tearing tissue.

3. Regarding Claim 10, the hook has (generally) the shape of a needle - long and thin.

4. Regarding Claim 11, the hooked tip is capable of being manufactured in many different ways.

5. Regarding Claims 19 and 22, the base element is generally planar [see Fig. 2].

6. Regarding Claim 24, Nelson's clip has a base element (26) that moves when the teeth move through the hole (20) in the locking element.

7. Regarding Claim 28, the aperture (20) contains threads as shown in Figure 5. The threads interdigitate with the teeth of the hooked tip.

8. Regarding Claim 30, Nelson discloses a method of forming the claimed clip, placing the hooked element in an aperture (20) of the base element, and pulling on a holder section (24) as shown in Fig. 5. The word "pulling" is considered to be sufficiently broad to include the bending/pushing/pulling that appears in Fig. 5.

9. Claims 34 and 36-39 lack novelty under PCT Article 33(2) as being anticipated by MILLER et al. With reference to Fig. 10 and regarding Claims 34, 38, and 39, Miller discloses a ring with a plurality of curved hooked members. Miller also discloses a rigid female member with a plurality of recesses.

10. Regarding Claim 36, the hooked elements flatten when inserted into the holes of the female member.

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Supplemental Box

To be used when the space in any of the preceding boxes is not sufficient)

11. Regarding Claim 37, the elements are capable of such an intended use.
12. Claims 6, 7, 13, 14, 20-23, 29, and 31-33, 35, 40, and 41 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a plurality of clips with all of the structure claimed. Neither does the prior art explicitly disclose a location on the clip that it intended to tear, as set forth in claims 13, 14, and 20.
13. Claims 1-41 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.